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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,685	11/21/2000	Eugeni A. Vaisberg	CYTOP007C2	5849

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EXAMINER

SHEINBERG, MONIKA B

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/718,685

Applicant(s)

VAISBERG ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-43, 45 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-43, 45 and 49-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) <u>2 sheets</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION***Response to Amendment A***

Applicants' arguments, filed 02 January 2002, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-43, 45 and 49-51, as necessitated by amendment, are rejected under 35 U.S.C. 102(b) as being anticipated by Giuliano et al (*J. of Biom. Screening*, 1997).

The rejection is maintained and reiterated from the previous office action mailed 23 October 2001. Applicants argue that Giuliano et al does not teach or suggest the capturing of morphological values from "a plurality of cells from one or more cell lines" (Amendment A, p. 5, 4th paragraph), however claims 40-43 and 45 do not require the limitation of "one or more cell lines". Giuliano does teach the application of the method upon a "plurality of cells" inherently in the process of high-content screening, which is done on "arrays of live cells" (figure 5, p. 253). The method of Giuliano et al, allows the HCS analysis of cells individually from a plurality, or "fields of cells" (p.252, 2nd column, line 1). The limitations of claims 49-51, such as "different cell lines" claim 49, are encompassed within "arrays of live cells". In addition, the number of times a method is done is not patentable distinction over the prior art. See MPEP § 2144.04 VI (B).

Applicants argue that Giuliano et al. does not teach or suggest any methods for data comparisons between experiments, however data comparison as such is not within the claims 40-

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43, 45, or 49. Thus the argument of the reference lacking data comparison is non-persuasive regarding claims 40-43, 45 and 49 due to the lack of data comparison within these claims. Data comparison or clustering does appear in claim 50. However due to the lack of clarity in the phrasing of lines 4-6, the comparing or clustering can potentially be interpreted as a listing of the degree of presence of each morphological value as presented in Figure 8 of page 255, in which “[i]mages and detailed data in a spread sheet for individual cells can be viewed separately or summary data can be plotted”; the cells demonstrated are HeLa cells (p. 253, 1st column, 1st paragraph). Thus data comparison arguments of the applicants are rendered non-persuasive regarding claim 50 and its dependent claim 51.

Applicants also argue that Giuliano et al. does not teach or suggest any methods for creating “footprints” that quantify and/or qualify the data. However, the claims only contain a generic analysis of the data attained by the determined property of manipulation, and not a specific analysis. Thus argument concerning the quantification/qualification of data is non-persuasive.

Applicants also argue that Giuliano et al. does not teach or suggest any specific information concerning the database or methods of analysis or search to be used with the database. However specific database information or method of analysis as such is not within the pending claims, thus these arguments are rendered non-persuasive.

Therefore, the arguments are non-persuasive to overcome the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

As necessitated by amendment, claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 is vague and indefinite due to the lack of clarity of the “comparing or clustering” step in lines 4-6. It is unclear as what is being compared or clustered: the comparison of degrees of presence of morphological values within one cell; comparison of these values to

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each other in different cells within a cell line or different cell lines; comparison of one or more cells of a cell line to an average or normal; clustering of the values dependent on the specific manipulated component from more than one cell; or clustering of cells dependent on similar values; and so forth. Thus the possible interpretations are confusing and unclear rendering the claim vague and indefinite.

Specification

The disclosure is objected to because of the following informalities: The appendix at the end of the specification does not conform to requirements for specification contents. See the MPEP § 608.01 ("PAPER REQUIREMENTS"):

2. (i) Lines that are 1 1/2 or double spaced;
- (ii) Text written in a nonscript type font (e.g., Arial, Times Roman, or Courier) lettering style having capital letters which are at least 0.21 cm (0.08 inch) high

The Appendix A in the specification is single spaced; and lettered in a style where the capital letters are approximately only 0.16 cm high.

Appropriate correction is required.

Information Disclosure Statement

References C-H of the information disclosure statement are not considered because as provisionals, they lack public publication dates which are necessary for documents to be considered. The information referred to therein has not been considered as to the merits.

Conclusion

No claim is allowed of the pending claims 40-43, 45 and 49-51.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 10, 2002

Monika B. Sheinberg
Art Unit 1631

MB

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER